UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,669	09/21/2001	Michael Garabedian	GARABEDIAN=1.1A	5735

7590 10/07/2003

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, DC 20001-5303

EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file

Office Action Summary	Application No.	Applicant(s)	
	09/816,669	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Ray Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method for screening and isolating cofactors for transcription factors , classified in class 435, subclass 7.31.

II. Claims 14, 15, 19 and 20, drawn to SEQ ID No. 4, classified in class 530, subclass 350.

III. Claims14, 16, 19 and 20, drawn to SEQ ID No. 6, classified in class 530, subclass 350.

IV. Claims 14, 17, 19 and 20, drawn to SEQ ID No. 8, classified in class 530, subclass 350.

V. Claims 14 and 18-20, drawn to SEQ ID No. 10, classified in class 530, subclass350.

VI. Claims 21-25, drawn to SEQ ID No. 3, classified in class 536, subclass 23.1.

VII. Claims21-25, drawn to SEQ ID No. 5, classified in class 536, subclass 23.1.

VIII. Claims 21-25, drawn to SEQ ID No. 7, classified in class 536, subclass 23.1.

IX. Claims 21-25, drawn to SEQ ID No. 9, classified in class 536, subclass 23.1.

X. Claim 26, drawn to a product – an antisense oligonucleotide as drawn to SEQ ID No. 4, classified in class 536, subclass 24.5.

XI. Claim 26, drawn to a product – an antisense oligonucleotide as drawn to SEQ ID No. 6, classified in class 536, subclass 24.5.

XII. Claim 26, drawn to a product – an antisense oligonucleotide as drawn to SEQ ID No. 8, classified in class 356, subclass 24.5.

XIII. Claim 26, drawn to a product – an antisense oligonucleotide as drawn to SEQ ID No. 10., classified in class 356, subclass 24.5.

XIV. Claims 27 and 28, drawn to an antibody as drawn to SEQ ID No. 4, classified in class 530, subclass 387.1.

XV. Claims 27 and 28, drawn to an antibody as drawn to SEQ ID No. 6, classified in class 530, subclass 387.1.

XVI. Class 27 and 28, drawn to an antibody as drawn to SEQ ID No. 8, classified in class 530, subclass 387.1.

XVII. Class 27 and 28, drawn to an antibody as drawn to SEQ ID No. 10, classified in class 530, subclass 387.1.

XVIII. Claims 29 and 30, drawn to a method of treatment using antibodies as drawn SEQ ID No. 4, classified in class 424, subclass 130.1.

XIX. Claims 29 and 30, drawn to a method of treatment using antibodies as drawn SEQ ID No. 6, classified in class 424, subclass 130.1.

XX. Claims 29 and 30, drawn to a method of treatment using antibodies as drawn SEQ ID No. 8, classified in class 424, subclass 130.1.

XXI. Claims 29 and 30, drawn to a method of treatment using antibodies as drawn to SEQ ID No. 10, classified in class 424, subclass 130.1.

XXII. Claims 31 and 32, drawn to a diagnostic method of identifying an inhibitor as drawn to SEQ ID No. 4, classified in 435, subclass 7.1.

XXIII. Claims 31 and 32, drawn to a diagnostic method of identifying an inhibitor as drawn to SEQ ID No. 6, classified in 435, subclass 7.1.

XXIV. Claims 31 and 32, drawn to a diagnostic method of identifying an inhibitor as drawn to SEQ ID No. 8, classified in 435, subclass 7.1.

XXV. Claims 31 and 32, drawn to a diagnostic method of identifying an inhibitor as drawn to SEQ ID No. 10, classified in 435, subclass 7.1.

XXVI. Claim 33 is drawn to a composition – an inhibitor, classified 514, subclass 2.

XXVII. Claim 34 is drawn to a method of inhibiting the interaction between androgen receptor and coregulatory protein, classified in 435, subclass 7.1.

Inventions in Group I and Groups II-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group I is a method of screening while Groups II-IX are drawn to a composition, each of which is drawn to a different nucleotide or amino acid sequence. Group I can be used to produce new strains of yeast with different growth requirements, having nothing to do with identification of the products comprising Groups II-IX. Furthermore, the method can be used to identify products altogether different from those comprising Groups II-IX, with different functions or different effects. As amongst Groups II-IX, as a matter of course distinct nucleotide or amino acid sequences are treated as separate inventions (e.g. even 99% homology does not necessarily confer a structure-function correlation), because proteins or genes with different nucleotide or amino acid sequences will have distinct and particularized function

correlate with specific regions that may be involved in protein-DNA, protein-protein or intra-molecular interactions. As such these compositions would inherently involve different functions, modes of operation or effects.

Groups X-XIII are each drawn to an antisense oligonucleotide molecule, which can for example be used in hybridization assays to probe RNA or DNA sample. Such a function or mode of operation is distinguished from the Group I method of screening and from Groups II-IX compositions. As amongst groups X-XIII there are different nucleotide sequences with inherently different functions and effects (e.g. the fact that each can hybridize with different templates is one example of a distinct effect).

Groups XIV-XVII are unrelated to the preceding groups because they are drawn to antibodies – a class of proteins with distinct modes of operation as compared to the method of identifying compounds in Group I or the compositions in Groups II-IX or the antisense composition of Groups X-XIII. For example antibodies themselves can be used to raise secondary antibodies, which can be used in immunoassays, having nothing to do with the functions or effects of the preceding groups. As amongst Groups XIV-XVII there are distinct amino acid sequences, each with an inherent distinct function correlating to its specific structure (i.e. sequence).

Groups XVIII-XXI are each drawn to a method of treatment using antibodies each drawn to a distinctly different structure (i.e. amino acid sequence). The method of treatment would require *in vivo* application with inherently different modes of operation, function or effects. For example the route of administration, the half-life of the antibody, the dosage and potential adverse affects are all modes of operation that are different as compared to any of the preceding

groups. Moreover the effects would be different comparatively. For example one antibody can have a different effect (e.g. dosage-dependent adverse reaction) when compared to antibodies drawn to a different protein. Since each antibody is drawn to a different protein each is a separate invention. In addition *in vivo* use, as is known in the art, inherently involves problem solving and obstacles that would not affect any of the preceding groups of claims. In addition subsequent groups are also unrelated because they do no require *in vivo* administration.

Groups XXII-XXV are each drawn to a diagnostic method identify a composition – an inhibitor or a particular protein-protein interaction. This effect is different than that of Group I (where the protein-protein interaction does not have to be inhibitory). In addition the mode of operation is different because there is an additional protein-protein interaction that is occurring not evident in any of the preceding groups. The effect is also different as compared to the compositions of Groups II-IX, the antisense oligonucleotides of Groups X-XIII, the antibodies of groups XIV-XVII or the method of treatment in Groups XVIII-XXI. The diagnostic method can be used independently from any of the preceding groups and the method identifies a composition that shares no commonality with any of the preceding compositions nor can be identified through any of the preceding methods. As amongst Groups XXII-XXV each distinct amino acid sequence constitutes a separate invention thus each group drawn to a distinct sequence is a separate invention.

Group XXVI is drawn to the actual inhibitor – product, where the preceding set (Groups XXII-XXV) are drawn to the process of producing the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another

and materially different process (MPEP § 806.05(f)). In the instant case as set of products can be identified through random selection from publicly available databases, chemically synthesized and assayed for functionality in selected cells to determine if the randomly selected composition has an inhibitory effect. Group XXVI as compared to the preceding groups is an unrelated invention because it has a different effect than any of the preceding groups – inhibition of a particular protein-protein interaction.

Group XXVII inheres the characteristics discussed as to inhibiting a specific interaction thus is distinguished from the preceding groups not involving such interaction. It is also an unrelated invention as compared to Groups XVIII-XXVI because it is a method of use compared to a method of making (XVIII-XXV) and product made (XXVI). Inventions in Group XXVI and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to raise antibodies instead of inhibiting the interaction in Group XXVII.

For the reasons given above these inventions are distinct and have acquired a separate status in the art as shown by their different classification. In addition each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (i.e. Group I or II or III) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in

compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanies by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph. D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

DAVID GUZO
PRIMARY EXAMINER